

Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Meeting Summary

December 6 & 7, 2004

Baltimore, Maryland

MONDAY, DECEMBER 6, 2004

INTRODUCTION AND WELCOME

Herb Kuhn and Rita Hostak provided an introduction and opened the second meeting of the PAOC. The welcome was followed by a summary of meeting ground-rules and decorum by the moderator, Robin Williams. The first presentation was provided by Mike Keane of CMS who described the timeline necessary for publishing and clearance of the Notice of Proposed Rule Making (NPRM), which will need to be completed by the end of 2005. He also clarified that quality and accreditation requirements do not need to be included in the proposed rule, so program structure issues will take priority in this PAOC meeting.

EXISTING DMEPOS COMPETITIVE BIDDING PROGRAMS

Tom Hoerger of RTI presented an overview of the DMEPOS competitive bidding programs with representation on the PAOC committee, including the Department of Veterans Affairs (VA), the Minnesota and Utah Medicaid programs, and PacifiCare Health Systems. The presentation described the history and scope of competitive acquisition for each organization; listing some of the included products, describing the contracting process, and describing accreditation requirements, quality evaluation, and access monitoring. Contract prices for oxygen supplies were provided for the two Medicaid programs, but no prices were included for the VA or PacifiCare. The VA presentation detailed that contracting can occur at the local, regional or national level for specific items, the provision of items and service, or service alone. The contracting process was reviewed, which is conducted by work groups consisting of physicians and individuals with expertise on product or quality evaluation and contracting personnel. The presentation described the accreditation of the VA, and that non-accredited suppliers

contracted with the VA fall under the scope of the VA's accreditation requirements. The VA presentation concluded by denoting some of the ways in which the VA and Medicare differ, including the fact that the VA is a medical provider, is itself accredited, and typically issues sole-source contracts. The presentation then moved on to the state Medicaid agencies. Utah's oxygen concentrator contract was described, including the fact that the goal of its implementation was to address access limitations in rural and low population areas within the state. Minnesota's contracts for oxygen concentrators and portable oxygen systems were described, and price ranges for contracts in the 14 Medicaid regions within the state were provided. The presentation pointed out that oxygen concentrator rental prices were below the Medicare fee schedule, but portable oxygen systems, while overall lower than the fee schedule, exhibited regional prices below and above the fee schedule. The presentation then described Minnesota's experience with contracting with hearing aid and wheelchair manufacturers, and indicated the difficulties that forced the state to abandon competitive acquisition for wheelchairs. The presentation concluded with an overview of PacifiCare's DME competitive bidding program, including a comment on contract areas and patient monitoring.

Following the presentation, the PAOC committee commented on the programs and their applicability to Medicare. The representatives from each program provided additional information and responded to questions from other members of the committee. Several members stated they thought that other competitive bidding programs were not applicable to Medicare, with several stating that VA costs should not be used for comparison. One member questioned the quality of the products included in the Utah program, and indicated that suppliers may have been underbidding in Minnesota. Questions about PacifiCare involved the use of beneficiary surveys and feedback from disease management programs for quality monitoring. The discussion then moved on to the possibility of contracting with manufacturers, including which products this may be appropriate for and whether it would be feasible to obtain service for products not provided by suppliers.

BIDDING ALTERNATIVES RELATED TO HCPCS CODES

The next presentation focused on the mechanics of bidding, including the use of product categories for grouping HCPCS, and whether bids should be based on categories, each item in a category, or some items in a category. The presentation was given in two sections, each followed by a discussion period. The first section presented three options, 1) Conduct a single bidding competition covering all DME subject to competitive bidding, 2) Conduct separate bidding competition for each product category, or 3) Conduct separate bidding competitions for each item. Advantages and disadvantages for each option were explored, including its impact on referral agents, bidding costs, supplier options and costs, and education requirements.

The discussion of the committee focused on the definition of product categories and the possible effects of selecting each option. Most members selected option 2 as the best, but many had some remaining concerns. Some members stated that "one-stop shopping" is

good, but only if suppliers have expertise in all items they will supply. There was additional comment about the possibility of contracting directly with manufacturers, or with direct manufacturer/suppliers, and how they could be expected to provide products in a product category that they do not produce. No members supported option 1, but there was some discussion over the feasibility of utilizing option 3, with one member stating this may be best for certain products.

Following discussion on the use of product categories in bidding, Tom Hoerger continued the presentation on alternatives to requiring bids on individual HCPCS codes. This presentation was premised on the choice made from the previous portion of the presentation. If option 3 were to be selected, this would require bids to be made on each HCPCS code. However, if options 1 or 2 were to be implemented, the program would face several options for bidding. Three options were presented, and as with the previous portion of the presentation, it was stressed that in general these options represented extremes and could be adapted or combined. The options included A) requiring bids for all HCPCS codes in a product category, B) requiring bidders to submit a single straight percent discount from the fee schedule for all items within a product category, and C) requiring bids for only a select number of high-volume and high-cost products within a category. It was stated that during the demonstration, the actual process more closely resembled option A in the first round, but then more closely paralleled option C in the later two bidding rounds. Advantages and disadvantages for each option were presented, including their effects on supplier and bidding costs. It was noted that during the first round of the demonstration, some product categories were found to include many codes that were rarely or never actually encountered, while a few codes dominated the overall reimbursement for the product category. However, it then became unclear what should happen to these items not included in bidding. For option B, the possibility was raised that prices differences relative to the fee schedule may not be uniform for all items within a product category.

Discussion on these options focused on possible combinations of options B and C, discussion over what should be done with items not included in bidding under option C, and concerns about selective bidding. One PAOC member stated that bidding should be based on a discount from the fee schedule for only a select number of items. Several members discussed what should be done to products within a product category that were excluded from bidding, including whether they should be discounted at the same rate as other items in the product category or remain at the fee schedule. Some members stated that it could be harmful to reduce reimbursement on non-bid items. It was also noted that non-bid items should remain open for any willing provider so winning suppliers were not awarded market share for items on which they did not need to bid. There was also discussion about the possibility of suppliers “cherry-picking” items to bid if selecting products on which to bid was left to their discretion.

TRANSITION POLICIES FOR CERTAIN RENTED ITEMS AND OXYGEN

The third presentation of the day was conducted by Elaine Myers of Palmetto GBA, and described the experience of using transition policies in the DMEPOS demonstration. The presentation described what the demonstration transition policies were, and what is mandated by the MMA. During the demonstration, capped rental agreements were preserved according to the original terms. This was meant to preserve existing supplier contracts, protect beneficiaries from losing earned equity in a capped rental item, and prevent winning suppliers from being required to assume provision of capped rentals with less than the full term remaining on rental payments. The demonstration also included policies to allow non-demonstration suppliers with pre-existing service relationships with beneficiaries receiving oxygen or nebulizer drug supplies and service to continue serving their customers at the new bid price. This policy was intended to minimize service disruptions.

During discussion, several members of the PAOC expressed their approval for the incorporation of such transition policies. Several asked for clarification of the demonstration policies, including what would happen for products that require additional supplies. Ms. Myers responded that ancillary items were permitted from non-demonstration suppliers. Another member of the committee commented on how quality and accreditation requirements would be met by non-winning suppliers that continued serving Medicare beneficiaries, and was told by the presenter that special evaluation and monitoring was devoted to non-winning suppliers during the demonstration. One member stated that such policies could be used for products such as diabetic test-strips.

BIDDING CYCLES

The final presentation on day one centered on bidding cycles, including their duration, staggered bidding, off-cycle bidding, and annual payment adjustments. The presentation noted that the MMA requires bidding to occur at least every three years, but that the bidding process in the demonstration required 6-9 months to complete. The presentation suggested that bidding could be staggered in different MSAs to reduce administrative requirements. Off-cycle bidding was described as an option that could be incorporated in the event that capacity or supplier choice requirements are not being met, or in the event of a new HCPCS item becoming available during a contract cycle. Finally, options were presented for off-cycle bidding, including relying on suppliers to anticipate product cost increases and factor these into their bids, provide annual payment adjustments based on several criteria, or allowing payment adjustments to occur based on unexpected, large increases in inflation.

During the discussion, most members stated their support for staggered bidding and payment adjustments in the event of high inflation. Many suggested that off-cycle bidding would be appropriate in case of insufficient capacity or beneficiary choice, although some members thought that new products should not be subject to competitive bidding. There were differing views on contract durations among committee members. Members representing suppliers argued for shorter contract durations, specifically two years, stating that longer durations could force suppliers out of the market. Members with program administration experience argued for longer durations to limit the

frequency of supplier transitions, which can prove disruptive and difficult to manage. The discussion then moved onto the number of DME suppliers, and whether pharmacies and physician offices should be considered suppliers and subject to competitive bidding and accreditation requirements. Some members wanted to regulate physician provision of DME supplies to their patients, requiring them to obtain accreditation and to submit winning bids. Other members argued that physicians provide these products as part of the standard of care, and often provide them for free for patients who cannot afford co-pays. Herb Kuhn of CMS stated that the competitive bidding program must not interfere with physician care.

PUBLIC COMMENTS

Following the agenda items, members of the public were given the opportunity to speak to the committee for five minutes, and eight individuals requested the opportunity to speak. The first individual stated she represented a manufacturers' association, and stated that their organization wants a web-cast or phone line available for viewing the meeting, a 90 day comment period for the NPRM, an open public comment session for the committee, and for CMS to revisit HCPCS codes, as some are too broad. She also stated that manufacturers will not have a role in the program unless they are direct suppliers. She stated that an analysis needs to be done by product for each local area to establish Medicare utilization and potential for savings, and wants to see how selected MSAs are distributed by DMERC region if they will be implementing the program.

The second individual stated that she wants the PAOC to produce conclusions or findings. She also stated that the DMERCs should be evaluated in terms of implementation as only one has experience from the demonstration. She stated that standards must be product specific, and expressed concern about comparing Medicare prices to prices from other programs.

One member of the audience spoke about his accreditation organization and what he felt were misconceptions about it by CMS. He described its experience and the fact that its standards are easy to understand.

An individual from a supplier stated that the fees of other programs are close to the Medicare rates. He also stated that he thought there were currently access issues in Polk County FL as he had difficulty setting up oxygen service for his customers who were visiting the area. Finally, he stated that the effect on small businesses needs to be considered.

A representative of a drug store association stated he was concerned about diabetic testing supplies, and could not understand why glucose monitors and strips had different HCPCS codes.

An individual representing a long-term care association stated that he thought that the administration of the program was being analyzed from the perspective of CMS, not providers. Responding to the bidding presentation, he stated that he did not want option

1, and that option 2 would depend on the product categories adopted. He wanted to know what would happen in regards to non-bid supplies, and said it would be difficult to bid on accessories that have to go to a specific product.

One member of the public stated his belief that the implementation timeline is infeasible. He also stated that the committee should reach consensus and deliver a single message to CMS.

The last individual to speak stated he was the director of a home medical equipment program at a major university. He stated that competitive bidding will interfere with physician care, and believes that lowered service will result in higher inpatient care utilization, which could wipe-out any savings from competitive bidding.

TUESDAY, DECEMBER 7, 2004

INTRODUCTION AND WELCOME

The second day of the PAOC meeting centered on competitive bidding scope and phase-in issues, in particular the criteria for selecting Metropolitan Statistical Areas (MSAs) and the selection of items for competitive bidding. The day began with a welcome from Rita Hostak, who also addressed comments made to her and to the committee by members of the public the previous day asking for the committee to produce recommendations. Ms. Hostak reiterated that the purpose of the committee was to advise and provide oversight for CMS during the design and implementation of competitive bidding and quality standards, not to produce findings and formal recommendations.

MSA SELECTION FOR DME COMPETITIVE ACQUISITION

Joel Kaiser of CMS provided an introduction to issues and requirements for the phase-in of MSAs for competitive bidding. Tom Hoerger then presented options for criteria for the selection of MSAs. The focus of the presentation was not on the actual selection of MSAs, but on possible criteria to use when selecting and prioritizing MSAs. The presentation reiterated the MMA requirements that competition occur in ten of the largest MSAs in 2007, 80 of the largest MSAs in 2009, and other areas thereafter, but that rural and low population areas may be exempted. The presentation listed several issues for the PAOC to consider, including how to define and interpret which MSA should be considered among the “largest”. Data for the top MSAs by total population, Medicare FFS enrollment, and allowed charges were presented, and the correlation and differences among them explored. The most striking result from the data is that the Miami-Fort Lauderdale-Miami Beach, FL MSA exhibits the highest allowed charges despite not being among the top five for population or enrollment. In addition to MSA rankings, some of the practical challenges of MSA selection were discussed, including varying geographic size, crossing state lines, crossing DMERC regions, and geographic diversity.

Following the presentation, discussion focused on whether implementation should follow a slower, cautious approach, or to focus early implementation on MSAs which could be used as a learning process for later implementation. Some committee members stated that smaller MSAs should initially be selected, and large MSAs should be reserved for later in the phase-in process. One member stated that he was not confident that the results of the demonstration in Polk County and San Antonio warrant reproduction of the program in large areas, and that starting in smaller areas would minimize risk. Others stated that administration of the program could be challenging, and that CMS and its implementing contractors should begin in more manageable markets as they overcome the learning curve. Some of these members argued that the language of the law was ambiguous and that any of the 50 or 60 largest MSAs should be under consideration.

Other members disagreed, stating that the program should begin in some of the very largest markets, or markets that exhibit special or difficult circumstances so the program will identify any problems early in implementation. Some members suggested that in addition to large markets, markets with large rural areas, markets that cross state and DMERC boundaries, and markets that were small or had a limited supplier market should be selected in the first round to serve as test cases.

PRODUCT SELECTION PHASE-IN FOR DME COMPETITIVE ACQUISITION

The second presentation of the day continued the theme of program phase-in, centering on the selection of products for inclusion in the early rounds of competitive bidding. Joel Kaiser introduced the presentation and reviewed the requirements, while Tom Hoerger presented the topic. The presentation began with a discussion of which products were specifically required and excluded by the MMA. Possible criteria for selection, in addition to product suitability to competitive bidding included products with the highest costs (allowed charges) and products with the highest potential for savings. The presentation then listed the product categories with the highest allowed charges, as calculated from Medicare claims. The presentation showed that the top three product categories (oxygen, wheelchairs, and nebulizers and related drugs) accounted for over 50 percent of allowed charges, while the top sixteen accounted for over 90 percent. The presentation then illustrated that while the products groups (based on DME policy groups) often included many individual HCPCS codes, in many cases a few codes dominate reimbursement for the entire product category. For example, among the wheelchairs and accessories policy group, the current HCPCS code K0011 accounts for over 50 percent of allowed charges. Three additional wheelchair codes accounted for nearly 24 percent of allowed charges, while many accessory and ancillary items accounted for relatively little reimbursement. The presentation then focused on additional issues for consideration, including potential for savings, the number of approved suppliers, products not specifically included by the MMA, complementary products, and whether the selection of items should be uniform across MSAs.

Discussion on this section covered many areas. Several members stated that some products exhibited special circumstances or challenges, and some members made a case that certain items should be excluded. Some members spoke about the issue of complementary products, and several mention diabetic testing supplies, noting that test strips had to be compatible with glucose monitors and this could cause problems in competitive bidding. However, one member stated that the VA has had great success with competitive acquisition for glucose monitors and strips, and mentioned that suppliers or manufacturers that won contracts for the supply of test strips were generally willing to provide glucose monitors for free. Some members stated that the changes that are occurring in the coding of wheelchairs will have an important effect on consideration of this product category for inclusion. Another concern was whether some products that required additional service, including the fitting and service of wheelchairs, would be affected. There was also some discussion of product categories and how they should be defined. One member with competitive bidding administrative experience stated his

concern with using broad product categories as this could make administration too difficult. He also stated that products such as wheelchairs, which exhibit a great deal of diversity within HCPCS codes, could pose problems. Several members stated that the selection of products should be informed by the level of service required for the item, and that special consideration be made to ensure sufficient service is provided to beneficiaries. Several members commented on the importance of quality standards for enhancing beneficiary care.

CONCLUSION

Following the discussion of project phase-in issues, Joel Kaiser of CMS spoke to the committee to clarify current Medicare payment practices. He described the process for defining product categories, when items are purchased or rented, what service is included in rental, and the capped rental process. Chester Robinson of CMS then discussed the priorities for PAOC agendas and the current status of work on quality standards, which CMS views as a critical part of the competitive bidding program. He emphasized that most of the requirements for quality standards do not need to be included in the regulation, and that while items necessary for regulation development process are of high priority for discussion by the PAOC, work is continuing on quality standards. He indicated that an inventory and analysis of accreditation organizations' quality standards is ongoing, and will be discussed in future PAOC meetings.

PUBLIC COMMENTS

The first individual to speak stated that he believed the committee should produce a final report of their recommendations, and that it should be completed before the NPRM process is completed.

The next person to speak stated that not having the quality standards published causes uncertainty. He also stated that the accreditation process can be lengthy, and that CMS should consider the time necessary for accreditation when issuing requirements.

An individual representing a large home oxygen supplier stated that the focus of the presentation on other competitive bidding programs was on price, and that Medicare causes more administrative costs than the VA. She stated that Medicare should attempt to reduce the administrative burden. She also stated that they wanted another evaluation of the DMEPOS demonstration to also consider re-hospitalization rates. She also wondered whether it was appropriate for the four DMERCs to administer the program when only one has experience in the competitive bidding demonstration. She also stated that CMS should conduct an analysis of beneficiaries with secondary payers.

The next individual represented another home oxygen supplier. He stated that VA contracts are very different than Medicare, in particular that VA contracts allow suppliers to predict 2nd and 3rd year price increases. He also reiterated that Medicare incurs high administrative burden for suppliers. He stated that the competitive bidding demonstration

should be re-evaluated to calculate savings based on fee reductions that have occurred since the demonstrations concluded.

An individual representing manufacturers of several products stated their desire for Medicare to establish work-groups to evaluate HCPCS, and to establish new codes for products of similar design, purpose and market price. She stated that direct manufacturer/suppliers should be permitted to bid on limited products, and not be required to supply all products in the product category. She stated that new HCPCS should not be subject to competitive bidding. Finally, she stated that the committee had too much representation from the wheelchair industry, and not enough respiratory care experience.

An owner of a supplier wanted to know if the problems encountered in the demonstration would be fixed. He also stated that low prices cannot be made-up in quantity, and that low prices will result in poor staffing, and in turn poor service.

The last individual to speak represented a supplier association. He mentioned that some MSAs, including Philadelphia not only cross state lines, but also cross DMERC regions, and this causes problems due to licensing and state law requirements. He implored the committee members to consider the plight of small suppliers that do not have the resources to serve on the committee. He suggested that each committee member visit a small supplier to observe their operations, and for future meetings to bring in clinicians, physicians, and product samples.